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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,578

02/27/2002

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ASA-1070

3832

24956 7590 02/05/2010
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EXAMINER

NAGPAUL, JYOTI

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/069,578	Applicant(s) SHIBUYA ET AL.	
	Examiner JYOTI NAGPAUL	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment filed on December 14, 2009 has been acknowledged. Claims 16-25 are pending.

Response to Amendment

Rejection of Claims 16-18 and 21-25 as being anticipated by Mimura (US 6080364) has been modified in light of applicants' amendments.

Rejection of Claims 19-20 as being unpatentable over Mimura in view of Hanaway has been modified in light of applicants' amendments.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16 and 22 recites the limitation "the rack supply line". There is insufficient antecedent basis for this limitation in the claim. It is believed that applicants intend to recite --the rack supply section--.
3. Claim 23 recites the limitation "transfer passages" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 24 recites the limitation "a rack" in line 4. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 25 recites the limitation "a rack" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 16-18 and 21-25** rejected under 35 U.S.C. 102(b) as being anticipated by Mimura (JP 10-097754) (English translation provided in US 6080364).

Regarding claims 16 and 22, Mimura teaches an automatic analyzer. The analyzer comprises ***an analysis unit*** (the system as a whole as shown in Figure 1) for analyzing specimens. Mimura further teaches ***a rack supply section*** (75). Applicants further recite the rack supply section (75) supplies “common racks holding patient specimens to be samples for the analysis by the analysis unit, and specific racks holding specific liquid to be repeatedly sampled as needed for analysis of the patent specimens.” Examiner notes that common racks and specific racks are recited in an intended use limitation and therefore are not positively recited. The claim limitation merely requires a rack supply section that is capable of supplying common racks holding patient specimens to be samples for the analysis by the analysis unit, and specific racks holding specific liquid to be repeatedly sampled as needed for analysis of the patent specimens. It is suggested that applicants positively recite common racks and specific racks to be of any patentable significance. Mimura further teaches ***a rack feed line*** (disclosed as means for transferring in col. 4, lines 54-55) connected to the rack supply section (75). Mimura further teaches ***a rack standby disk*** (76) connected

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to the rack feed line (disclosed means for transferring in col. 4, lines 54-55). Applicants further recite the rack standby disk that is connected to the rack feed line receives "the common and specific rack from the rack feed line." As stated above, the common and specific racks are not positively recited as they are recited in an intended use limitation. Applicants must positively recite the common and specific racks to have any patentable significance over the prior art. Mimura further teaches **a rack recovery line** (25).

Applicants further recite "for receiving the common racks from the rack standby disk."

Again, the common and specific racks are not positively recited as they are recited in an intended use limitation. Applicants must positively recite the common and specific racks to have any patentable significance over the prior art. Mimura further teaches **a**

control unit (40) connected to the rack supply section (75), the rack feed line (disclosed means for transferring in col. 4, lines 54-55), the rack standby disk (76) and the rack recovery line (25) controlling transfer of the common racks and the specific racks from the rack supply section (75) to the rack standby disk (76). The control unit (40) further controls rotating and stopping of the rack standby disk (76) in a state such that the plurality of common racks and specific racks are made to standby thereon in a mixed state and controls transferring of the racks on the rack standby disk (76) towards a rack recovery section after treatment. The common and specific racks as recited in the functioning of the control unit. Mimura teaches specific sample racks to be used repeatedly like reference sample racks (77 or 74) and control sample racks (77 or 74) held by the standby disk (76). These racks are equivalent to applicant's recited common and specific racks. (Refer to Col. 4, Lines 49-67 to Col. 5, Lines 1-26) The

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control unit (40) of Mimura controls rotating and stopping of the rack standby disk (76) in a such a state such that the plurality of reference sample racks and control sample racks are made to standby in a mixed state and controls transferring of the racks towards a rack recovery section. (Refer to Col. 4, Lines 49-67 to Col. 5, Lines 1-26)

Applicants further recite "a rack recovery section". This structural feature is not positively recited and therefore is of no patentable significance over the prior art.

Mimura further teaches **a reading device** (71) for reading discriminating information of the common and the specific racks prior to the rack standby disk (76) receiving the common and specific racks from the rack feed line (disclosed as means for transferring in col. 4, lines 54-55) and disposed proximate to the rack feed line (disclosed as means for transferring in col. 4, lines 54-55). Mimura further teaches **a rack transfer means** (20) that transfers the common and specific racks from the rack standby disk (76) to a specimen sampling position on the analysis unit (the system as a whole as shown in Figure 1) and returns the common specific racks from which the specimens and specific liquids have been sampled in the specimen sampling position to the rack standby disk (76). Mimura further teaches the control unit (40) controls transfer of the common and specific racks, the control sample racks (77) or the reference sample racks (74) as disclosed in Mimura, based on the discriminating information read by the reading device (71) so that the common racks are carried toward the rack recovery section after treatment, and the specific racks are kept standing by on the rack standby disk (76) until a subsequent time of measurement of the specific rack. (Refer to Col. 5, Lines 1-51) (Refer to Col. 24, Lines 57-68 to Col. 25, Lines 1-11) Regarding claim 22, applicants

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recite the control unit (40) controls "transfer of the common and specific racks based on the discriminating information read by the reading device and after a preceding rack is returned to the rack standby disk from the specimen sampling position, a subsequent rack is transferred to the sampling position via the rack transfer means." Applicants do not positively recite a preceding rack and a subsequent rack in body of the claim as a whole. Thus, a preceding rack and a subsequent rack is of no patentable significance over the prior art. The control unit (40) of Mimura is capable of transferring different types of racks.

Regarding claim 17, the rack standby disk (76) is disposed in a rack delivery unit (70). (See Figure 1)

Regarding claim 18, Applicants recite "wherein a position of the rack standby disk for receipt of a pretreatment rack from the rack feed line in which a specimen is to be sampled and a position of the rack standby disk for carrying-out of an aftertreatment rack from which a specimen has been sampled are used in common." This limitation is considered a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. The recited process or intended use limitation is accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between

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the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114). Additionally, Examiner would like to point out that applicants recite an “pretreatment rack” and “aftertreatment rack” in an intended use limitation and therefore are not positively recited. The recited pretreatment and aftertreatment racks are of no patentable significance over the prior art as they are not positively recited.

Regarding claim 21, applicant recites “wherein said control unit **controls** transfer of an emergency rack as one of the racks holding a specimen, **which** needs urgent measurement, said emergency rack being **received** by said rack standby disk, and when said rack standby disk **holds** the emergency rack, another one of the racks for which sampling and treatment of a specimen is **being performed** in said analysis unit, is **suspended and temporarily returned** onto the rack standby disk, wherein the emergency rack is **transferred** to the specimen sampling position of the analysis unit from the rack standby disk **after** the sampling and treatment of the specimen and

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wherein the **suspended** rack is then **transferred** to the specimen sampling position on the analysis unit from the rack standby disk **so that** the sampling and treatment for the specimen are **resumed** for the suspended rack.” The above recitation is clearly a functional limitation. The language does not constitute a limitation in any patentable sense in apparatus claims. The control unit of Mimura is clearly capable of performing the claimed function as it is automated system. Mimura further teaches a control unit (40) controlling transfer of the racks in a manner that after a preceding rack is returned to the rack standby disk (70) from the specimen sampling position (4A or 4B), a subsequent rack is transferred via the rack transfer means.

Regarding claim 23, Mimura teaches the control unit (40) transfers of the racks in a manner that so long as the sum of the number of racks actually held on the rack standby disk (76) and the number of racks present on transfer passages (20 and 25) of the rack transfer means is smaller than the number of racks that can be held on the rack standby disk. This control unit (40) is capable of performing the above limitation as it is an automated system.

Regarding claim 24, the analysis unit (the system has a whole shown in figure 1) is one among multiple units including biochemical analysis units (3A-3G) which analyze items of biochemical analysis and immunity analysis units which analyze items of immunity analysis. The control unit controls transfer of the racks (74 or 77) in a manner that when a rack holding a specimen, for which items of biochemical analysis and items of immunity analysis are to be analyzed, is received on the rack standby disk (76), the rack is transferred to the immunity analysis unit (3A-3G) from the rack standby disk (76)

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before being transferred to the biochemical analysis unit, and after the rack having been subjected to sampling and treatment of the specimen in the immunity analysis unit is returned to the rack standby disk (76), the rack is transferred to a specimen sampling position on the biochemical analysis unit from the rack standby disk (76).

Regarding claim 25, the control unit (40) controls transfer of the racks in a manner that until re-measurement is decided on the basis of results of analysis of a specimen sampled at the analysis unit, a rack having been subjected to sampling and treatment of the specimen is kept standing by on the rack standby disk (76), and when re-measurement is necessary, the rack (74 or 77) having stood by is again transferred to the specimen sampling position on the analysis unit from the rack standby disk (76). (Refer to Col. 7, Lines 59-63 and Col. 24, Lines 57-67 to Col. 25, Lines 1-11)

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mimura in view of Hanaway.

Refer above for the teachings of Mimura.

Mimura fails to teach the rack standby disk is disposed in an evaporating protecting chamber, in which air is maintained higher in humidity than an outside air.

Hanaway teaches a specimen tray assembly for use in an automatic analyzer. The assembly comprising of an evaporation protecting chamber (See Figures 2, 4 and 5).

It would have been obvious to a person of ordinary skill in the art to modify the device of Mimura such that the rack standby disk is disposed in an evaporating protecting chamber as suggested by Hanaway to achieve the predictable results of reducing evaporation and there is no undue evaporation of the contents of the cuvettes. (See Col. 7, Lines 28-31)

Response to Arguments

12. Applicant's arguments filed on December 14, 2009 have been fully considered but they are not persuasive. In the remarks, applicants address the amendments made to independent claims 16 and 22. However, no acknowledgement is made as to what claimed feature is not taught or disclosed by the primary reference, Mimura. The amendments to the claims are addressed in the above rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI NAGPAUL whose telephone number is (571)272-1273. The examiner can normally be reached on Monday thru Friday (10:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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